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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,757	06/24/2003	Billy R. Martin	02940232AA	7329

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WHITHAM, CURTIS & CHRISTOFFERSON, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER	
OWENS, AMELIA A	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,757	MARTIN ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 11/1/2005

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6* is/are allowed.

6)☒ Claim(s) *7 and 9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 10/1/2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 8 has been canceled. Claims 17-20 have been added. Claims 1-7,9-20 are pending. Drawings, 4 sheets, were filed.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-7,11,12,14,15 under 35 USC 112, 2nd paragraph has been dropped as the claims have been amended.

3. Claims 7,10-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for obesity; pain; loss of appetite; nausea and vomiting, does not reasonably provide enablement for inflammation; convulsions; spasticity associated with multiple sclerosis; impaired cognition; alcohol, tobacco, marijuana dependence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's remarks have been fully considered but are not found persuasive. The LeFoll reference has a 2005 date which is after applicants 2003 filing date, suggesting applicants did not have possession of the invention; cannabinoids to treat drug addition, at the time the invention was filed. It is noted that USP 6949582 and USP 6900236 both have 2005 patent dates that are after applicants 2003 filing date.

USP 5596106 does not have any data indicating that cannabinoids enhance cognition. The disclosure is prophetic at best.

Smith, The safety of cannabinoids for the treatment of multiple sclerosis, Expert Opin. Drug Saf. (2005) 4(3), 443-456 @ 443 teach that treatment of MS using cannabinoids is not yet convincing. Thus, cannabinoids are not known to treat MS or the symptoms, such as spasticity, associated with MS. Note the date is after applicants 2003 filing date suggesting applicants did not have possession of the invention.

Applicants are claiming 'blocking the effects of the cannabinoid receptor' which is defined as 'inverse agonism' in the background section of the specification. The language merely describes applicants' intent for the compound. Applicant is invited to come in with a declaration utilizing the claimed compounds via the claimed pathway showing inverse agonism of the cannabinoid receptor. Applicants are also invited to demonstrate that inverse agonism

results in effective treatment. Inverse agonism/blocking the effects of the receptor per se is not a viable utility. Further, Pertwee, Inverse agonism and neutral antagonism at cannabinoid CB1 receptors, Life Sciences 76 (2005) 1307-1324, @ 1307 teach inverse agonsism of cannabinoid receptors. However, the reference has a 2005 date suggesting that applicants were not in possession of the invention at the time the application was filed. T

Cannabinoids are known to treat pain; nausea/vomiting, obesity and loss of appetite. See respectively Walker, Cannabinoids and pain, PMID: 11854769 (2001); Berry, Tetrahydrocannabinol and endocannabinoids in feeding and appetite, Pharmacology & Therapeutics 95 (2002) 185-190 @ 188 column 2 section 5. Structurally similar compounds would be expected to have similar properties. Thus, the claimed cannabinoid derivatives would be expected to treat pain; nausea/vomiting, obesity and loss of appetite.

4. Claim16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompasses as yet unidentified 'effects' associated with blocking the receptor, a description of which is not found in the specification.

What is meant by 'effects'? What disease/condition/symptom are applicants trying to prevent/inhibit?

5. Claims 9, 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 encompasses as yet unidentified compounds having a sulfonamide moiety, a description of which is not found in the specification.

The phrase 'compound having a sulfonamide moiety which functions....' is employed with no indication given as to what they really are. One should be able, from reading of the claims, determine what that claim does or does not encompass. Why? Because that claim preclude others from making, using, or selling that compound for 20 years. Therefore, one must

know what compound is being claimed. In the pharmaceutical area, declarations under 37 CFR 1.132 are often employed to set forth the advantage of a particular substituent. The definition and claiming of compounds is extremely important in the claims of the application.

Applicant should not be able to preempt future work of others by means of claims to compounds they themselves did not make and test. Conception of the intended compounds should not be the role of the reader. Applicant should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely and invitation to experiment. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48 at page 53.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. That compound used for any purpose is taken from the public in a 20 year monopoly by applicants. Then, the public is entitled to know what compound they cannot use. Yet the claim in not specific to that compound. The public cannot tell what they may not use. As applied to pure compounds, in re Cavallito and Gray, 134 USPQ 370, and in re Sus and Schaefer, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

For claim 16, What is meant by 'effects'? What disease/condition/symptom are applicants trying to prevent/inhibit?

Certain Observations

6. Claims 1-6 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMELIA AVERILL OWENS
PRIMARY EXAMINER